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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/470,874	12/22/1999	MARC MEHRZAD JALISI	ACS-58267 (1700X)	6721

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EXAMINER

MACNEILL, ELIZABETH

ART UNIT	PAPER NUMBER
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3767

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/470,874

Applicant(s)

JALISI ET AL.

Examiner

Elizabeth R. MacNeill

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15, 17, 19-27 and 29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 17, 19-27 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to applicants amendments submitted 15 February 2007.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-15,17,19-27 and 29 are rejected under 35 U.S.C. 103(a) as obvious over THOME et al (US 5,776,080) in view of FAGAN et al (WO 96/25969, cited by applicant).

Regarding claim 1, Thome teaches a heat-treated elongate member comprising a composite core (150), the composite core section including an inner core (154) formed of Hipercor wire, and a layer formed of a superelastic material (178, Nitinol), and a second layer concentrically arranged about the layer formed of superelastic material (176), wherein the layer is arranged about the inner core (See Fig 25) (Col 16 lines 54-end).

Thome does not teach that the inner core is formed of a precipitation hardened material. Fagan teaches a precipitation hardened material (stainless steel) for use in a medical guidewire (Abstract). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the precipitation hardened material of Fagan with the guidewire of Thome as an alternate material.

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Regarding claim 8, Examiner takes the "flexible body overlying the distal section" to be resin 176. Thome teaches the precipitation hardenable material to be Hiberco 50B, which contains cobalt and iron (and trace elements), and Fagan discloses an alloy of nickel, cobalt, molybdenum and chromium (MP35N, page 17 lines 19) (also applicable to claims 10,13,14,15).

Regarding claim 26, Thome further discloses a flexible coil (162, 182) disposed at a distal end of a distal section of the guidewire, wherein the precipitation hardened material and superelastic material extend from the proximal section to at least through a part of a length of the flexible coil. The phrasing "a distal end of a distal section" is believed to apply to any point at least halfway from the proximal end of the catheter, since any cross-section of the catheter past the half way point would be "a distal section" and each section would have a distal end.

Regarding claim 27, Thome further discloses that the distal section is tapered (Fig 27)

Regarding claims 2-4, the modulus of elasticity of the composite elongate is about 28×10^6 to 29×10^6 (Fagan page 17 line 23).

Regarding claims 5-7, the ultimate tensile strength of the composite elongate is 300 k.s.i. (Fagan page 17 line 26).

Regarding claim 9, the composite core is precipitation hardenable stainless steel (Fagan)

Regarding claim 17, the inner core and outer layer are independently formed (Thome)

Regarding claim 19, the first layer is Nitinol (Thome)

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Regarding claims 20,21, 29 a second layer (158) is disposed at least in part concentrically about the first layer, second layer of substantially the same material as the first layer (Thome)

Regarding claims 22,24, the elongate member is a guidewire (Thome)

Regarding claims 11 and 12, Thome discloses the claimed invention except for the use of less than 1% nickel precipitation hardened stainless steel. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use nickel free stainless steel, since it has been held to be within the general skill of worker in the art to select a known material on the basis of its suitability for the intended use a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Response to Arguments

Applicant's arguments filed 15 February 2007 have been fully considered but they are not persuasive. Regarding claim 1, the phrasing "arranged about" does not have to mean outside of or exterior to the superelastic layer, so resin layer 176 meets this limitation since it is concentric to the superelastic layer. Regarding claim 8, the resin is the flexible body "distinct from the first layer" and overlies the distal section (Fig 5).

Regarding claims 26 and 27, the phrasing "a distal end of a distal section" is believed to apply to any point at least halfway from the proximal end of the catheter, since any cross-section of the catheter past the halfway point would be "a distal section" and each section would have a distal end.

Conclusion

3. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth R. MacNeill whose telephone number is (571)-272-9970. The examiner can normally be reached on 7:00-3:30pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ERM

*Elizabeth
M. Hill
3/12/07*

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER
Kevin C. Sirmons